

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF NEW MEXICO**

THE REGENTS OF THE UNIVERSITY  
OF NEW MEXICO,

Plaintiff,

vs.

No. CIV 99-577 JC/WWD

GALEN D. KNIGHT, an individual;  
and TERENCE J. SCALLEN, an individual,

Defendants.

**FINDINGS OF FACT AND CONCLUSIONS OF LAW**

THIS MATTER comes before the Court after a bench trial that commenced on June 25, 2001, and concluded on July 3, 2001. After considering the evidence, oral arguments, and written briefs, the Court makes the following Findings of Facts and Conclusions of Law.

**FINDINGS OF FACT**

**A. Jurisdictional Facts**

1. The Plaintiff University of New Mexico (“UNM”) is a corporate body established under the Constitution and laws of the State of New Mexico.
2. Defendant Galen D. Knight, Ph.D. is a resident of the State of New Mexico.
3. Defendant Terence J. Scallen, MD., Ph.D. is a resident of the State of California.
4. The allegations of Counts I and III raise issues that arise under the Patent Laws, 35 U.S.C. § 1 *et seq.* Count III of the Amended Complaint arises under 35 U.S.C. § 256 and 28 U.S.C. § 2201.

**B. Procedural History**

5. The Court entered summary judgment in favor of Plaintiff on Count II of the Complaint, holding that the University is the owner of all right, title, and interest in and to the Beta-Alethine Patents and Applications (as defined in the Amended Complaint).
6. The Court entered summary judgment on Count IV, holding that Defendants Knight and Scallen breached their contractual obligations with the University by failing to execute assignments to the Vitaletheine Patents and Applications and Beta-Alethine Patents and Applications (as defined in the Amended Complaint).
7. The Court entered summary judgment holding that Defendants are the only joint inventors of one of the Vitaletheine Issued Patents, U.S. Patent No. 5,370,868 (Count III).
8. The Court dismissed Counts V, VI, and VII of the Amended Complaint.

**C. Patents and Patent Applications**

9. The patent application (Serial No. 08/317,548) that matured into United States Patent No. 5,578,313 (the “313 Patent”), entitled “Therapeutic Uses of Vitaletheine Modulators in Neoplasia,” was filed on October 4, 1994, as a divisional application of Application Serial No. 07/928,725, filed on August 12, 1992. The ‘313 Patent was issued on November 26, 1996, with Defendants Knight and Scallen listed as inventors. Defendants Knight and Scallen signed a declaration of Inventorship stating they were the joint inventors of the subject matter claimed in Application Serial No. 07/928,725.

10. The patent application (Serial No. 08/463,732) that matured into United States Patent No. 6,096,536 (the “‘536 Patent”), entitled “In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy Beta-Alanyl-Taurine,” as amended, was filed on June 5, 1995, as a continuation application of United States Application Serial No. 07/941,926. The ‘536 Patent was issued on August 1, 2000, with Defendants Knight and Scallen listed as inventors. Defendants Knight and Scallen signed a declaration of Inventorship stating they were joint inventors of the subject matter claimed in Application Serial No. 07/941,926.
11. The United States Patent Application Serial No. 08/463,784 (the “‘784 Application,”) entitled “In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine,” as amended, was filed on June 5, 1995, as a continuation application of a divisional application of Application Serial No. 07/941,926, with Defendants Knight and Scallen named as the inventors. The ‘784 Application is pending before the United States Patent and Trademark Office (“USPTO”). Defendants signed a declaration of Inventorship as to Application Serial No. 07/941,926.
12. United States Patent Application Serial No. 08/466,143 (the “‘143 Application”), entitled “Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases,” was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, with Defendants Knight and Scallen named as the inventors. The ‘143 Application is pending before the USPTO. Defendants signed the declaration of Inventorship regarding the United States Application No. 07/910,892.
13. United States Patent Application Serial No. 08/469,697 (the “‘697 Application”),

entitled “Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases,” was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, naming Defendants Knight and Scallen as the inventors. The ‘697 Application is pending before the USPTO. Defendants signed a declaration of Inventorship regarding the United States Application No. 07/910,892.

14. The ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, and the ‘697 Application are collectively referred to as the “Patents and Applications.”

**D. Amendments to the Patents and Applications**

15. Plaintiff made amendments to the molecular structures of certain organic compounds disclosed and claimed in the specifications of the Patents and Applications. The amendments were made subsequent to the filing of the applications during the ordinary course of prosecution.
16. Plaintiff amended the Patents and Applications by correcting the molecular structure of “vitaletheine V<sub>4</sub>” with the molecular structure named “beta-alanyl-aurine” (the “beta-alanyl-aurine Amendment”).
17. Plaintiff also amended the Patents and Applications by correcting the molecular structure of “benzyl derivative of vitaletheine” with the molecular structure named “carbobenzoxy beta-alanyl-aurine” (the “carbobenzoxy beta-alanyl-aurine Amendment”).
18. The USPTO initially rejected the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment to the Patents and Applications

based on new matter.

19. The USPTO, however, subsequently accepted the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment in both the specification and claims to the Patents and Applications after further review. Three examiners of the USPTO, all knowledgeable in the necessary technology, accepted as true and accurate the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment as containing subject matter that is neither new nor in contravention of the Patent Laws, including the prohibition against new matter under 35 U.S.C. § 132.
20. The beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment deleted vitaethine modulator structures from the claims.
21. Defendants disagree with the Amendments and maintain that the structures as set forth in the Patents and Applications prior to the Amendments are the correct molecular structures for the organic compounds.
22. Defendant Knight filed protests and other documents with the USPTO regarding the Amendments.
23. No amendment was made to the specification of the application maturing into U.S. Patent No. 5,370,868 that altered the molecular structure of any compound disclosed in the application as filed.

**E. Synthesis of the Compounds**

24. Dovetail Technologies, Inc. (“Dovetail”) is a licensee of the Plaintiff. Dovetail retained Hauser Chemical Research, Inc. (“Hauser”), under the direction of

Christopher Murray, Ph.D., (“Dr. Murray”), to synthesize vitalethine, vitaletheine V<sub>4</sub>, and the benzyl derivative of vitaletheine, for use in preclinical studies and clinical trials by Dovetail.

25. Dr. Murray is an expert in both synthetic organic chemistry and in process chemistry development of organic compounds.
26. The Food and Drug Administration licensed Hauser to make synthetic organic compounds for use as active pharmaceutical ingredient materials. Hauser has made numerous different active pharmaceutical ingredient materials in compliance with Good Manufacturing Practice standards required by the Food and Drug Administration.
27. Hauser, under Dr. Murray’s directorship, employs the following analytical techniques to analyze and characterize organic compounds: one and two-dimensional carbon-13 nuclear magnetic resonance (<sup>13</sup>C-NMR), proton nuclear magnetic resonance (<sup>1</sup>H-NMR), electrospray mass spectroscopy elemental analysis, and infrared spectroscopy.
28. The initial synthetic procedures for vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine used by Hauser and Dr. Murray followed the precise specifications and procedures described in the Patents and Applications.
29. Dr. Murray and Hauser synthesized the organic compound denoted as “the benzyl derivative of vitaletheine” using the exact synthetic specifications stated in the Patents and Applications on thirteen distinct occasions.
30. Dr. Murray and Hauser synthesized the organic compound denoted as “vitaltheine

V<sub>4</sub>" using the exact synthetic specifications stated in the Patents and Applications on five occasions.

31. The organic compounds initially synthesized by Dr. Murray and Hauser using the synthetic specifications for vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine as stated in the Patents and Applications had the same characteristics as the above named compounds. In addition, the organic compounds were made in accordance with the methods and steps described in the Patents and Applications and were the same organic compounds as described in the Patents and Applications, as identified by the methods of manufacture, <sup>13</sup>C-NMR data in the Patents and Applications, <sup>1</sup>H-NMR data in the Patents and Applications, and other data and descriptions in the Patents and Applications.
32. Upon synthesizing vitaletheine V<sub>4</sub> and the benzyl derivative of viateltheine utilizing the specific methods as described in the Patents and Applications, Dr. Murray and Hauser then modified the synthetic methods using accepted techniques of process chemistry in order to optimize yield and manufacturing processes. Both compounds made by Dr. Murray and Hauser following the modified synthetic processes were the same organic compounds as those initially produced by Dr. Murray and Hauser utilizing the same processes as described in the Patents and Applications for vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine, as verified by various tests including one- and two-dimensional <sup>13</sup>C-NMR and <sup>1</sup>H-NMR, electrospray mass spectroscopy, elemental analysis and infrared spectroscopy. Plaintiff contends that one- and two-dimensional <sup>13</sup>C-NMR and <sup>1</sup>H-

NMR is the most definitive analytical technique for analysis, characterization, and identification of organic compounds.

33. Dr. Murray and Hauser then conducted literature searches, and identified an alternative means of synthesis for the compounds based on the “Feuer method.” Identifying an alternative method of synthesis and demonstrating that the same organic compound results is a recognized means of verifying the molecular structure and identity of an organic compound. Through the Feuer method, Dr. Murray and Hauser produced the exact organic compounds as those made using the methods detailed in the Patents and Applications for vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine. This method proves that the molecular structures determined by Dr. Murray and Hauser for the above organic compounds as defined in the Patents and Applications are correct.
34. The organic compounds that resulted when Dr. Murray and Hauser used the exact methods described in the Patents and Applications for synthesis of vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine did not have the same molecular structures as depicted in the Patents and Applications for vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine.
35. The organic compounds that Dr. Murray and Hauser synthesized using the methods depicted in the Patents and Applications for the synthesis of vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine were inherent in and the product of the methods so described in the Patents and Applications.
36. Dr. Murray and Hauser determined that vitaletheine V<sub>4</sub> and the benzyl derivative

of vitaletheine did not have the molecular structures that Defendants assigned to them in the Patents and Applications.

**F. Determination of the Amended Molecular Structures**

37. In order to determine the correct molecular structures, Dr. Murray asked nationally and internationally known experts, including professors from the University of Colorado, experts at Hauser, and members of Dovetail's scientific advisory board to analyze and determine the correct molecular structures of the compounds called vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine as described in the Patents and Applications.
38. Dr. Murray determined that vitaletheine V<sub>4</sub> should accurately be denoted as beta-alanyl-taurine and that the benzyl derivative of vitaletheine should accurately be denoted as carbobenzoxymethyl-beta-alanyl-taurine.

**G. Inability to Synthesis Vitaletheine**

39. As described in the Patents and Applications, Dr. Murray and Hauser repeatedly made beta-alanine, the primary starting material for vitaletheine. Dr. Murray and Hauser performed a formal structure proof of the resulting beta-alanine, thereby proving that the resulting compound had the same structure as the known structure of beta-alanine. This included development of a reference standard of beta-alanine, with analytical tests including two-dimensional NMR, elemental analysis, purity tests, in addition to other tests confirming that beta-alanine was in fact made.
40. Dr. Murray and Hauser attempted, on at least twenty-six occasions, to synthesize

the organic compound called “vitalethine” as described in the Patents and Applications. Dr. Murray and Hauser followed the exact methods described in the Patents and Applications, and they followed modifications thereof based on the described method of synthesis and known organic chemistry methodologies. Dr. Murray and Hauser further communicated with Defendant Knight concerning the synthetic method, and incorporated suggestions from Knight. Dr. Murray and Hauser also followed modifications in the method of synthesis as described by Defendants Knight and Scallen in a publication subsequent to the Patents and Applications. No organic compound resulted from these attempts meeting the description of “vitalethine” contained in the Patents and Applications. The primary resulting product obtained by Dr. Murray and Hauser was beta-alethine, which was the primary starting material described in the Patents and Applications used in the synthesis of “vitaletheine.”

#### **H. Confirmation of the Synthesis and Molecular Structures**

41. After Hauser reported the results, Plaintiff retained an expert consulting firm, Professional Analysis, Inc. (“PAI”), under the supervision of J. Shield Wallace, Ph.D.(“Dr. Wallace”), to synthesize and characterize organic compounds in accordance with the methods described in the Patents and Applications.
42. The synthetic procedures followed by Dr. Wallace and PAI for vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine were in accordance with the methods described in the Patents and Applications.
43. The organic compounds synthesized by Dr. Wallace and PAI that resulted from the

methods described in the Patents and Applications for synthesis of vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine did not have the molecular structures of vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine as depicted in the Patents and Applications.

44. Dr. Wallace determined that the organic compounds described as vitaletheine V<sub>4</sub> and the benzyl derivative of vitaletheine did not have the molecular structures assigned to these compounds by the inventors in the Patents and Applications as filed.
45. Dr. Wallace determined that vitaletheine V<sub>4</sub> was beta-alanyl-aurine and that the benzyl derivative of vitaletheine was carbobenzoxy-beta-alanyl-aurine.
46. Dr. Wallace and PAI attempted on three separate occasions to synthesize the organic compound called vitalethine as described in the Patents and Applications, following the exact methods therein. No organic compound resulted from these attempts meeting the description of vitalethine contained in the Patents and Applications.
47. Following the methods described in the Patents and Applications for the synthesis of vitalethine, the primary resulting product obtained by Dr. Wallace and PAI was beta-alethine.

**I. Existence of Vitalethine**

48. The organic compound called vitalethine in the Patents and Applications is not a part of any Amendment at issue.
49. Dr. Knight testified that he was the only person he knew of who had successfully

synthesized vitalethine.

**J. Structures of the Amendments are Inherent in the Patents and Applications**

50. The molecular structures disclosed in the beta-alanyl-aurine Amendment and in the carbobenzoxy beta-alanyl-aurine Amendment are implicit in and are an inherent characteristic of the written disclosures and specifications as filed in each of the Patents and Applications.

**L. Presumption of Correctness**

51. Defendants have not overcome the presumption of correctness as to the Patents and Applications wherein the Amendments have been allowed.

**CONCLUSIONS OF LAW**

1. The Court has personal jurisdiction over the parties.
2. Venue is properly laid in the District of New Mexico pursuant to 28 U.S.C. § 1400(b).
3. The issues raised in this case necessarily depend on one or more substantive questions of United States Patent Law.
4. The relief sought in Count III pursuant to 35 U.S.C. § 256 necessarily arises under the United States Patent Law for which federal courts have exclusive jurisdiction.
5. The Court has subject matter jurisdiction over the claims now pending.
6. The last sentence of 35 U.S.C. § 132 provides: “No amendment shall introduce new matter into the disclosure of the invention.” If new matter in contravention of 35 U.S.C. § 132 is introduced during prosecution of a patent application, the claims depending on or incorporating such new matter are invalid under 35 U.S.C.

§ 112. See *Waldmar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.2d 556, 558 (Fed. Cir. 1994); *Transco Prod., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 558 (Fed. Cir. 1994); *SDS USA, Inc. v. Ken Specialties, Inc.*, 122 F.Supp.2d 533, 544 (D.N.J. 2000).

7. Determination of whether an amendment introduces new matter “depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter.” *Brooktree Corporation v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1993). The rule applied is “that a structural formula may be corrected without violation of 35 U.S.C § 132, if ‘there is sufficient evidence in the record to show the (proposed structure) to be an inherent characteristic of the subject matter so identified.’” *Ex parte Marsili*, 214 U.S.P.Q. 904, 906 (Bd. Pat. App. 1979) (quoting *In re Magerlein*, 346 F.2d 609, 611 (C.C.P.A. 1965)). The Court finds that the organic compounds described in the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment inherently had, when the Patents and Applications were filed, and now have, the molecular structures given in the Amendments. On multiple occasions, Plaintiff attempted the synthesis of the compounds as reflected in the Patents and Applications. Plaintiff’s results reflected the organic compounds in the beta-alanyl-aurine Amendment and the carbobenzoxy beta-alanyl-aurine Amendment. Plaintiff also was unable to create the organic compound called vitalethine. Plaintiff verified these result using different experts, tests, and methodologies. Thus, the organic compounds described, exemplified, and claimed

in the Patents and Applications inherently had the molecular structures of the organic compounds as reflected in the Amendments. Accordingly, the Amendments did not add new matter.

8. Furthermore, a determination by the Patent and Trademark Office that an amendment does not introduce “new matter” as defined in 35 U.S.C. § 132 is entitled to an especially weighty presumption of correctness:

A patent is presumed valid, and this presumption is based in part on the expertise of the patent examiners presumed to have done their job. This presumption, which may be viewed as a presumption of administrative correctness, as applied to a new matter determination was discussed by our predecessor court, which stated that "the fact that the Patent Office allows . . . an amendment without objection thereto as new matter (within the meaning of 35 U.S.C. § 132) is entitled to an especially weighty presumption of correctness."

*Brooktree Corporation v. Advanced Micro Devices, Inc.*, 977 F.2d at 1574-75;

*accord, In re Smythe*, 480 F.2d 1376, 1385 n. 5, (CCPA 1973); *Technicon*

*Instruments Corp. v. Coleman Instruments, Inc.*, 255 F.Supp. 630 (N.D.Ill. 1966),

*aff'd*, 385 F.2d 391 (7th Cir. 1967). In this case, a total of three different

Examiners of the USPTO, each skilled in the relevant technology, have considered

and accepted the beta-alanyl-aurine Amendment and the carbobenzoxy

beta-alanyl-aurine Amendment as properly filed and as containing subject matter

that was not new or in contravention of the Patent Laws, including specifically the

“new matter” prohibition of 35 U.S.C. § 132. In addition, the evidence shows that

each Examiner in the USPTO took the question of new matter seriously, and

demanding rigorous and exhaustive proof before allowing the Amendments.

9. The Amendments do not, as a matter of law, introduce “new matter” into the Patents and Applications in contravention of 35 U.S.C. § 132.
10. Defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the ‘313 Patent and the ‘536 Patent are invalid.
11. Defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the Amendments introduced “new matter” into the Patents and Applications in contravention of 35 U.S.C. § 132.
12. Defendants Knight and Scallen are the properly named and sole inventors of the Patents and Applications as amended.
13. Plaintiff is the true and lawful owner of all right, title and interest to the Patents and Applications, including the ‘313 Patent, the ‘536 Patent, the ‘784 Application, the ‘143 Application, and the ‘697 Application, together with any patent or application, foreign or domestic, that is a continuation or divisional application of any of the foregoing, or which is a continuation or divisional application of a predecessor of any of the foregoing.
14. Defendants Knight and Scallen are the only, joint and properly named inventors of the ‘313 Patent and the ‘536 Patent.
15. Defendants Knight and Scallen are the only, joint and properly named inventors of the inventions disclosed in the ‘784 Application, the ‘143 Application, and the ‘697 Application, including without limitation the Amendments.
16. A patent is presumed valid. *See* 35 U.S.C. § 282. As Defendants contend, U.S. Patent No. 5,370,868 is therefore presumed valid. Moreover, Plaintiff is the true

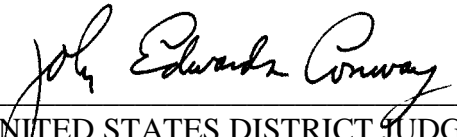
and lawful owner of all right, title and interest to U.S. Patent No. 5,370,868, as to which no amendment to the structure of any compound therein was made, and all other patent applications included within the Vitaletheine Patents and Applications as to which no amendment was made as to the structure of any compound included therein.

### **CONCLUSION**

For the reasons set forth above, and based on the facts adduced at trial, the Court finds that the Amendments to the Patents and Applications in dispute, which changed the structural formula of certain compounds, do not constitute new matter in violation of 35 U.S.C. § 132. Accordingly, judgment is rendered in favor of Plaintiff.

On a final note, when parties are unable to resolve their differences and proceed to trial, a court is forced to find for either a plaintiff or a defendant in accordance with the law. This case is troublesome because it involves a dispute, at its simplest level, over a potential cure for certain forms of cancer. While parties certainly should have an opportunity to litigate and explore the contours of their legal rights, possibly justice would be better served, at times, if a court could order the parties to cooperate and search for the greater good in a dispute. Unfortunately, the Court does not have such discretion, and the real losers in this case are the cancer patients who must await a more promising treatment for their devastating diseases.

WHEREFORE, a judgment shall be entered in accordance with these Findings of Facts and Conclusions of Law.

  
UNITED STATES DISTRICT JUDGE

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